

**REMARKS**

Upon entry of the forgoing amendments claims 31-35, 40-44, 67-69, 74-79 and 84 are pending in the application. Claims 36-39, 45-66, 70-73 and 80-83 have been withdrawn. Claims 31 and 67 have been amended to clarify the subject matter claimed therein. The amendments do not introduce any new subject matter within the meaning of 35 U.S.C. §132. Therefore, entry of the amendments is respectfully requested.

**REJECTIONS UNDER 35 U.S.C. §103(a)**

By way of introduction, Applicants submit that none of the cited references, individually or in combination, suggests that phytosphingosine or its derivatives would have a slimming effect on the skin. Applicants likewise submit that the combination of phytosphingosine or its derivative with other active agents known for their lipolytic activities to create a synergistic is not taught in the prior art. Specifically, the synergy is directly related to the fact phytosphingosine acts by complimentary mechanism on the synthesis of leptin.

Despite the generic teachings of the cited references, the specific bases of the rejections is made using an a posteriori knowledge of the art presented in the teachings of the instant application.

**Jackson, et al. in view of Bombardelli, et al.**

The Examiner has rejected claims 67, 69 and 74-76 under 35 U.S.C. §103(a) as being obvious over Jackson, et al., U.S. Patent No. 5,578,641, and further in view of Bombardelli, et al., U.S. Patent No. 5,679,358.

Applicants traverse this rejection. Each and every limitation of the presently claimed invention is not taught or suggested in the combination of references.

The teachings of Jackson et al. have been outlined in the previous responses, and Applicants herein submit that Jackson et al. relates to a composition for topical application to the skin comprising at least one ceramide pathway intermediate or precursor thereof. The presence of the ceramides precursor or pathway intermediate enables obtaining a higher level of ceramides in the stratum corneum, which leads to a number of advantages such as skin anti-aging effects. Because Jackson et al. does teach phytosphingosine as a ceramide precursor, Jackson et al. may be considered

as teaching that phytosphingosine may be used in a cosmetic composition as a ceramide precursor and consequently as an anti-aging agent. As previously submitted, Jackson et al. does teach the use of phytosphingosine for the eradication or reversal of skin aging, removal of rough or dry skin, or improving the lost of elasticity and flexibility of the skin. However, Jackson et al. do not teach or suggest the use of phytosphingosine as a lipolytic agent.

The secondary reference, Bombardelli et al. teaches compositions containing esculoside alone or in combination with an adenylate cyclase stimulator and/or phosphodiesterase inhibitors is useful for improving micro-circulation and chronic venous deficiency, such a cellulitis. Likewise, Bombardelli et al. teach that another consequence of the action of esculoside on micro-circulation is that it may be used to improve the early signs of skin aging.

Applicants submit that despite the Examiner's contention, sufficient motivation to combine the references has not been provided. One of skill in the art is well aware that there are numerous ways to combat skin aging. However, the products which are useful to fight skin aging do not have an impact on combating cellulitis or otherwise act to produce a slimming effect.

The compositions as claimed in claim 67, 69, and 74-76 relate to the specific combination of phytosphingosine and at least one lipolytic agent. As such, the subject matter of claims does have a structural difference over the cited art despite the Examiner's assertions to the contrary.

Specifically, the invention claimed has a structural difference over the cited art since it claims the use of the specific combination of phytosphingosine with a lipolytic agent, which is not recognized in the cited art. The instant claims are directed to the new and unexpected use of phytosphingosine as a slimming agent, which was in no way identified in the cited art.

Therefore, it is apparent that the unexpected new use discovered by the inventors is unobvious for one skilled in the art and support patentability of the composition.

With respect to claim 69, the Examiner alleges Jackson, et al. disclose the use of ceramide pathway such as phytosphingosine in a composition for topical application on the skin. However, Jackson, et al. do not teach the critical combination of phytosphingosine with a lipolytic agent as claimed in claim 67, upon which claim 69 depends.

With respect to the Examiner's statements concerning claim 74, while Bombardelli, et al. do teach providing an adenylate cyclase stimulator, said stimulator is in combination with esculoside. In contrast, the instant claims are directed to the critical combination of phytosphingosine with a lipolytic agent, which can be adenylate cyclase stimulator.

Applicants respectfully submit that since the patentability of claim 67 has been established, that the remaining claims which depend from claim 67 are likewise patentable.

Accordingly, the Examiner is asked to reconsider and withdraw this rejection to claims 67, 69 and 74-76.

**Jackson, et al. in view of Bombardelli, et al. further in view of Streekstra et al.**

The Examiner has rejected claim 68 under 35 U.S.C. §103(a) as being obvious over Jackson, et al., above, in view of Bombardelli, et al., above, and further in view of Streekstra, et al., WO 00/53568.

Applicants traverse this rejection. Each and every limitation of the presently claimed invention is not taught or suggested in the combination of references.

Jackson, et al. and Bombardelli, et al. are discussed above.

As previously submitted, Streekstra, et al. teach topical application of salts of sphingoid base derivatives in the treatment of conditions associated with dry skin, inflammation and/or microbial activity, i.e., eczema, psoriasis, atopic dermatitis, acne, dandruff, mouth and/or lip infections, mycoses, various other skin infectious diseases or vaginal infections, as well as, wounds, burns, and overall normalization of skin flora. Specifically, Streekstra et al. disclose sphingoid base derivatives having an improved efficacy due to their increased solubility in water. As with Jackson et al. and Bombardelli, Streekstra, et al. do not teach or suggest the use of phytosphingosine as a slimming agent.

Furthermore, claim 68, which depends from claim 67, relates to a hydrochloride salt of phytosphingosine and does not change the patentability which is already obtained for claim 67.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

**Jackson, et al. in view of Bombardelli, et al. further in view of Andre et al.**

The Examiner has rejected claim 77 under 35 U.S.C. §103(a) as being obvious over Jackson, et al., above, in view of Bombardelli, et al., above, and further in view of Andre et al., U.S. Patent No. 5,709,864.

Applicants traverse this rejection. Each and every limitation of the presently claimed invention is not taught or suggested in the combination of references.

Jackson, et al. and Bombardelli, et al. are discussed above. Andre, et al., has been discussed in previous responses.

As previously submitted, Andre, et al. teach a cosmetic or pharmaceutical dermatological composition comprising an effective quantity of a plant extract of the genus Tephrosia, i.e., T. purpurea, which are used for anti-aging applications. Andre et al. teaches that the extract is linked to activity as a stimulating agent for the enzyme adenylate cyclase. As such Andre et al. do not remedy the deficiencies of the primary references.

Furthermore, claim 77, which depends from claim 75, which ultimately depends from claim 67, relates to a composition wherein the adenylate cyclase enzyme activating agent is an extract of Coleus forskohlii and therefore does not change the patentability which is already obtained for claim 67.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

**Jackson, et al. in view of Andre et al.**

The Examiner has rejected claims 67, 69, 74 and 78-79 under 35 U.S.C. §103(a) as being obvious over Jackson, et al., above, in view of Andre et al., above.

Applicants traverse this rejection. Each and every limitation of the presently claimed invention is not taught or suggested in the combination of references.

Jackson, et al. and Andre, et al. are discussed above.

As previously submitted, Jackson, et al. do not teach the combination of phytosphingosine with a lipolytic agent. Rather, Jackson, et al., are limited to the use of phytosphingosine for the treatment of wrinkles or skin aging. Likewise, Andre, et al. provide no such teaching.

The Examiner alleges that it would have been obvious to one of ordinary skill in the art to combine the extracts of Andre, et al. in the wrinkle treating compositions of Jackson, et al. However, Applicants respectfully submit that such motivation is possible only in light of impermissible hindsight and knowledge of the instantly claimed subject matter. It has not been properly shown how one would be motivated to combine two compositions designed to treat aging skin in order to arrive at a composition designed to reduce subcutaneous fat. As such, contrary to the Examiner's contention, the cited references do not teach compositions which are intended for the same purpose as the claimed methods and compositions, and upon this basis a prima facie case of obviousness has not been established.

As noted above, the compositions as claimed in claims 67, 69, and 74-79 relate to the specific combination of phytosphingosine and at least one lipolytic agent with a structural difference over the cited art stemming therefrom.

The claimed subject matter has a structural difference over the cited art because it is directed to the specific combination of phytosphingosine with a lipolytic agent. Such a combination is not recognized in the cited art. The instant claims are directed to the new and unexpected use of phytosphingosine as a slimming agent, which was in no way identified in the cited art.

Accordingly, the Examiner is asked to reconsider and withdraw this rejection.

**Bombardelli, et al. in view of Jackson, et al.**

The Examiner has rejected claims 31-32, 34-35 40-42 and 84, under 35 U.S.C. §103(a) as being obvious over Bombardelli, et al., above, in view of Jackson, et al., above.

Applicants traverse this rejection. Each and every limitation of the presently claimed invention is not taught or suggested in the combination of references.

The teachings of Bombardelli, et al. and Jackson, et al. have been outlined above, as well as, in the previous responses. Applicants respectfully submit that neither Bombardelli, et al. nor Jackson, et al. teach the use of phytosphingosine as a lipolytic agent.

The methods claimed in claim 31-32, 34-35, 40-42 and 84 relate to the use of compositions having the specific combination of phytosphingosine and at least one lipolytic agent. As such, the subject matter of claims does have a structural difference over the cited art despite the Examiner's assertions to the contrary. In fact, the Examiner acknowledges that this combination is new over the prior art.

As stated previously through out this response, it is apparent that the unexpected new use discovered by the inventors is unobvious for one skilled in the art and support patentability of the method of use of the instant composition.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.



**Bombardelli, et al. in view of Jackson, et al. further in view of Streekstra et al.**

The Examiner has rejected claim 33 under 35 U.S.C. §103(a) as being obvious over Jackson, et al., above, in view of Bombardelli, et al., above, and further in view of Streekstra, et al., above.

Applicants traverse this rejection. Each and every limitation of the presently claimed invention is not taught or suggested in the combination of references.

Each of the cited references is discussed above and in previous responses.

None of the cited references teach or suggest the use of phytosphingosine as a slimming agent.

Furthermore, claim 31, which depends from claim 33, relates to a hydrochloride salt of phytosphingosine and does not change the patentability which is already obtained for claim 31.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

**Bombardelli, et al. in view of Jackson, et al. further in view of Andre et al.**

The Examiner has rejected claims 43-44 under 35 U.S.C. §103(a) as being obvious over Bombardelli, et al., in view of Jackson, et al., above, and further in view of Andre et al., all above.

Applicants traverse this rejection. Each and every limitation of the presently claimed invention is not taught or suggested in the combination of references.

Each of the cited references has already been discussed.

As previously submitted, Andre, et al. teach a cosmetic or pharmaceutical dermatological composition comprising an effective quantity of a plant extract of the genus Tephrosia, i.e., T. purpurea, which are used for anti-aging applications. As such Andre et al. do not remedy the deficiencies of the primary references.

Furthermore, claims 43-44, which depend indirectly from claim 31, relate to methods of use of a composition wherein the adenylate cyclase enzyme activating agent is an extract of Coleus forskohlii or of Tephrosia purpurea and therefore does not change the patentability which is already obtained for claim 31.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

**CONCLUSION**

In view of the foregoing, Applicants respectfully request the Examiner to reconsider and withdraw the restriction requirement, and to examine all of the claims pending in this application.

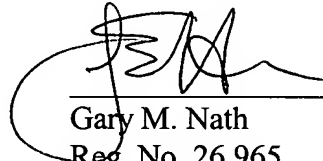
If the Examiner has any questions or comments regarding this matter, he is welcomed to contact the undersigned attorney at the below-listed number and address.

Respectfully submitted,

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